

INFORMATION COLLECTION REQUEST

EPA ICR Number 2030.01

**Reliability, Validity, and Variability in Behavioral Determinants of Drinking Water  
Disinfection By-Product Exposure**

March 2002

National Center for Environmental Assessment  
Office of Research and Development  
The United States Environmental Protection Agency

and

Dr. David Savitz, *et al.*  
The University of North Carolina-Chapel Hill  
School of Public Health

## TABLE of CONTENTS

	<u>Page</u>
<b>I. Part A of the Supporting Statement</b>	
1. Identification of the Information Collection .....	1
(a) Title of the Information Collection .....	1
(b) Short Characterization / Abstract .....	1
2. Need for and Use of the Collection .....	2
(a) Need / Authority for the Collection .....	2
(b) Practical Utility / Users of the Data .....	3
3. Nonduplication, Consultations, and Other Collection Criteria .....	4
(a) Nonduplication .....	4
(b) Public Notice Required Prior to ICR Submission to OMB .....	4
(c) Consultations .....	5
(i) Federal Register Announcement .....	5
(ii) Consultations .....	5
(d) Effects of Less Frequent Collection .....	7
(e) General Guidelines .....	7
(f) Confidentiality .....	8
(g) Sensitive Questions .....	8
4. The Respondents and the Information Requested .....	8
(a) Respondents / SIC Codes .....	8
(b) Information Requested .....	8
(i) Data Items, including Record-keeping Requirements .....	8
(ii) Respondent Activities .....	9
5. The Information Collected — Agency Activities, Collection Methodology, and Information Management .....	9
(a) Agency Activities .....	9
(b) Collection Methodology and Management .....	10
(c) Small Entity Flexibility .....	10
(d) Collection Schedule .....	10
6. Estimating the Burden and Cost of the Collection .....	11
(a) Respondent Burden .....	11
(b) Respondent Costs .....	11
(i) Labor Costs .....	11
(ii) Capital and Operations and Maintenance Costs .....	12

## TABLE OF CONTENTS cont.

	<u>Page</u>
(iii) Capital / Start-up vs. Operations and Maintenance (O&M) Costs . . . .	12
(iv) Annualizing Capital Costs . . . . .	12
(c) Agency Burden and Cost . . . . .	12
(d) Respondent Universe and Total Burden and Costs . . . . .	15
(e) Bottom Line Burden Hours and Cost . . . . .	15
(i) Respondent Tally . . . . .	15
(ii) The Agency Tally . . . . .	15
(f) Reasons for Changes in Burden . . . . .	16
(g) Burden Statement . . . . .	16
 <b>II. Part B of the Supporting Statement</b>	
1. Survey Objectives, Key Variables, and Other Preliminaries . . . . .	17
(a) Survey Objectives . . . . .	17
(b) Key Variables . . . . .	17
(c) Statistical Approach . . . . .	17
(d) Feasibility . . . . .	18
2. Survey Design . . . . .	19
(a) Target Population and Coverage . . . . .	19
(b) Sample Design . . . . .	19
(i) Sampling Frames . . . . .	19
(ii) Sample Size . . . . .	19
(iii) Stratification Variables . . . . .	20
(iv) Sampling Method . . . . .	20
(v) Multi-stage Sampling . . . . .	20
(c) Precision Requirements . . . . .	20
(i) Precision Targets . . . . .	20
(ii) Nonsampling Error . . . . .	21
(d) Questionnaire Design . . . . .	21
3. Pretests and Pilot Tests . . . . .	23
4. Collection Methods and Follow-up . . . . .	24
(a) Collection Methods . . . . .	24
(b) Survey Responses and Follow-up . . . . .	24

## TABLE OF CONTENTS cont.

	<u>Page</u>
5. Analyzing and Reporting Survey Results .....	25
(a) Data Preparation .....	25
(b) Analysis .....	25
(c) Reporting Results .....	26
<b>III. Attachments</b>	
Attachment 1. Full Text of 24-Hour Recall (with instructions) .....	27
Attachment 2. Full Text of Telephone Questionnaire .....	33

## **PART A of the SUPPORTING STATEMENT**

### **Section 1. Identification of the Information Collection.**

#### **1. (a) Title of the Information Collection**

Reliability, Validity, and Variability in Behavioral Determinants of Drinking Water Disinfection By-Product Exposure

**OMB Control Number:**

#### **1. (b) Short Characterization / Abstract:**

This study aims to characterize the reliability, validity, and variability of questionnaire-based information on water usage patterns collected in environmental epidemiologic studies. The study builds on a study entitled “Drinking Water Disinfectant By-products and Spontaneous Abortion” funded by the American Water Works Association Research Foundation (AWWARF). The present study will add a substudy component to the parent AWWARF study which is already in the field. This ICR provides for reinterview of a 10 % sample (300 women) of the parent study participants for a reliability substudy and an additional 10 % sample (300 women) for a validity substudy. Human behaviors (i.e., water usage patterns over time) that will affect exposure to an ambient level of a particular chemical, is an important source of variability and this has not been well characterized in previous drinking water epidemiology studies. Better characterization of the reliability, variability, and validity of this information, generally obtained through recall in a questionnaire, will decrease uncertainties related to misclassification of the exposure variables and enhance our ability to more clearly interpret the validity and accuracy of reported study findings. All participation and responses are voluntary. Confidentiality of responses will be maintained.

The data are being collected by the University of North Carolina in collaboration with the EPA’s National Center for Environmental Assessment under Cooperative Agreement No. CR828455-01-0. The cooperative agreement was solicited and awarded through an open, competitive process to which the successful awardee voluntarily responded. The present survey is not associated with any rule-making process within the Federal government. Instead, this research will help demonstrate the usefulness of water usage data for epidemiologic application and improved data collection methodologies for cumulative risk assessments. Additionally, the data collection will enable the specific evaluation of different sources of exposure misclassification within the ongoing parent study and provide quantitative data enabling correction of misclassified exposure-related variables.

The (completely voluntary) survey will have two phases. Mothers enrolled in the parent study who agree to participate (N = 600) will be asked to report water usage through two different mechanisms. Phase I will include a survey of approximately 15 minutes in length as part of the subjects’ follow-up interview (N = 300). Phase II will consist of three (30-minute)

24-hour recalls sent to mothers who express interest in this component (N = 300). The total number of respondents is 600. The only cost to respondents will be their time, for a total of 525 hours. The burden estimates are based on administration of 300 questionnaires and 900 24-hour recalls. The total respondent cost estimate is \$11,340. Additionally, all respondents will be provided monetary incentives for their participation.

Data will be stored on UNC/EPA computer files that protect respondent confidentiality. Summary results from the study will be available to the participants and disseminated by the UNC study team

## **Section 2. Need for and Use of the Collection.**

### **2. (a) Need / Authority for the Collection**

The statutory authority for this cooperative agreement is the Safe Drinking Water Act (SDWA), as amended, Section 1442, Paragraph (1)(a)(b) and (d) limits awards under this section to improved methods (i) to identify and measure the existence of contaminants in drinking water (including methods which may be used by State and local health and water officials), and (ii) to identify the source of such contaminants; improved methods to identify and measure the health effects of contaminants in drinking water; improved methods for providing a dependably safe supply of drinking water, including improvements in water purification and distribution, and methods of assessing the health related hazards of drinking water. As explained in Section 1, the proposed data collection will result in clearer interpretation of drinking water epidemiology studies and make their results more relevant and usable for input into cumulative risk assessment problems related to drinking water exposures. This clearly fits under this statutory authority.

While this information is not required for a particular Agency decision, it will be of use to EPA scientists, the academic research community, and citizens who are engaged in investigating the reliability and validity of behavioral determinants of water usage for epidemiologic application, as well as the development of cumulative risk methodology relevant to drinking water exposures.

This research ICR supports directly the Government Performance and Results Act (GPRA) goals for EPA in the following way:

Under ORD GPRA Goal Area 2 (Safe Drinking Water), subobjective 2.1.7: By 2010, provide a stronger scientific basis for future implementation of the Safe Drinking Water Act (SDWA)--the main report generated from this ICR will satisfy NCEA's FY05 APM: *'Report on the reliability, validity and variability in behavioral determinants of drinking water exposures among women of reproductive age* in support of the FY07 APG: Provide a sound scientific basis for future potential revision of the Stage 2 DBP rule.

## **2. (b) Practical Utility / Users of the Data**

### *Practical Utility*

The data produced by the surveys will fulfill the practical utility requirements of the Paperwork Reduction Act as defined in 5 CFR 1320.3(1): “practical utility means the actual, not merely the theoretical or potential, usefulness of information to or for an agency...”

EPA anticipates receiving survey data and analytic results that will provide new information about the reliability, validity, and variability of behavioral determinants of drinking water exposure. These will be immediately applicable to agency research and will help fulfill the provisions of a cooperative agreement commitment as well as an ORD/NCEA GPRA deliverable in 2005.

Limited previous knowledge of water usage variability and the uncertainties due to exposure misclassification in previous reproductive studies warrant the proposed analyses. The findings of the survey will support EPA’s effort to develop cumulative risk assessments from drinking water.

The completion of the surveys, the collection of the data, and the analytic findings it produces will fulfill the objectives of the cooperative agreement that University of North Carolina has with EPA. That agreement calls for completion of surveys by participants of the parent study. The proposed surveys seek to estimate water usage during pregnancy comparing two survey methods.

### *Users of the Data*

EPA plans to use the information from the reliability and validity analyses, along with findings from the parent study and other reproductive studies, to further develop cumulative risk methodology for drinking water exposures. This data will also aid other scientists in interpreting the literature on disinfection by-products and reproductive outcomes by providing general information on the reliability and variability of questionnaire-based information collection procedures in a cohort of women of reproductive age.

### **Section 3. Nonduplication, Consultations, and Other Collection Criteria.**

#### **3. (a) Nonduplication**

Three related articles were identified. The first — “How Well Does a Telephone Questionnaire Measure Drinking Water Intake” by Robertson B, Forbes A, Sinclair M, Black J in *Australian and New Zealand Journal of Public Health*, 2000, Volume 24, Number 6, pages 619-622 — describes a reliability and validity study on water intake for children and adults. The present study will focus solely on pregnant mothers and will expand the scope of the data collection to total water usage which incorporates not only ingestion but other routes of exposure including inhalation and dermal absorption. The second — “Assessment of Water Use for Estimating Exposure to Tap Water Contaminants” by Shimokura G H, Savitz D A, Symansk E in *Environmental Health Perspectives*, 1998, Volume 106, pages 55-59 — describes work from North Carolina conducted earlier by a member of the UNC survey team (Savitz). The third — “Exposure to Tap Water During Pregnancy” by Zender R, Bachand A, Reif J in *Journal of Exposure Analysis and Environmental Epidemiology*, 2001, Volume 11, pages 224-230 — describes work on pregnant and non-pregnant mothers in Colorado. Both of these studies evaluated a certain sub-population of pregnant women (NC-highly educated cohort; CO-low SES group) to evaluate water usage. The present study will improve on these findings by evaluating water usage patterns of pregnant women across different socioeconomic levels and geographical regions. The size of the present study, breadth of behavioral factors examined, and the scope of ancillary data available from the main study would make this the most thorough study of the validity and reliability of reported behavioral differences on DBP exposure conducted thus far.

The following databases were reviewed and contained no additional related references: Medline, Water Resource Abstracts, Environment Abstracts, Biological Abstracts, and Science Citation Index. In the course of the ORD internal and external review of this cooperative agreement, no duplication of research effort was detected.

#### **3. (b) Public Notice Required Prior to ICR Submissions to OMB**

In accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), EPA published a notice in the *Federal Register* on July 27, 2001 announcing that the reliability and validity surveys of pregnant mothers was available for public comment. A copy of the *Federal Register* notice is attached as an appendix to this document (Attachment 3).

The survey authors and EPA received no requests for the survey after the *Federal Register* notice was published and no comments were received on the proposed surveys.

### 3. (c) Consultations

#### *(i) Federal Register Announcement*

EPA / ORD /NCEA published a Federal Register Announcement on Friday, July 27, 2001; (FR 66 39159). No comments were received.

#### *(ii) Consultations*

EPA in conjunction with University of North Carolina has undertaken a number of consultations in developing this project, including academic experts, intra-agency staff and key stakeholders. The following individuals reviewed the EPA cooperative agreement which proposed and approved funding for this data collection:

<b>Consultant</b>	<b>Address</b>	<b>Phone / Email</b>
Glenn Suter, Ph.D. Science Advisor	U.S. EPA/NCEA 26 W. Martin Luther King Dr. Cincinnati, OH 45268	513-569-7808 <a href="mailto:suter.glenn@epa.gov">suter.glenn@epa.gov</a>
Chandrika Moudgal, M.S. Chemist	U.S. EPA/NCEA 26 W. Martin Luther King Dr. Cincinnati, OH 45268	513-569-7078 <a href="mailto:moudgal.chandrika@epa.gov">moudgal.chandrika@epa.gov</a>
Linda Teuschler, M.S. Mathematical Statistician	U.S. EPA/NCEA 26 W. Martin Luther King Dr. Cincinnati, OH 45268	513-569-7573 <a href="mailto:teuschler.linda@epa.gov">teuschler.linda@epa.gov</a>
John A. Bukowski, D.V.M., Ph.D., M.P.H. Staff Epidemiologist	Exxon/Mobil Biomedical Sciences, Inc. 1545 Rte. 22, PO Box 971 LF278 Annandale, NJ 08801-0971	908-730-1105 <a href="mailto:jabukow@erenj.com">jabukow@erenj.com</a>
Rebecca L. Calderon, Ph.D., M.P.H. Chief, Epidemiology & Biomarkers Branch	National Health and Environmental Effects Laboratory, Office of Research and Development, U.S. EPA, Research Triangle Park, NC 27711	919-966-0617 <a href="mailto:calderon.rebecca@epa.gov">calderon.rebecca@epa.gov</a>
Evelyn O. Talbott, Dr. P.H., M.P.H., Associate Professor of Epidemiology	Department of Epidemiology Graduate School of Public Health University of Pittsburgh Pittsburgh, PA 15217	412-624-3074 <a href="mailto:eot1@pitt.edu">eot1@pitt.edu</a>

The reviewers listed above uniformly supported the development of the data collection instruments as part of the cooperative agreement. The University of North Carolina has a broad range of survey researchers included on the research team (Drs. Savitz, Singer, Hertz-Piccioto, Weinberg, Hartmann, and Thorp). Outside consultants with expertise in related fields were also asked to review the study design and questionnaires of the parent study.

Reviewers of the survey plan have made constructive suggestions about the structure of the questionnaires and sample selection; they expressed enthusiasm for the data collection. After developing the survey methodology and constructing the first version of the pilot survey instrument, the telephone questionnaires were pre-tested by the Battelle research team. Input from these subjects and comments elicited from peer reviewers was used to refine the questionnaire for administration. The following individuals have had input in the planning process and survey design and were supportive of our plans to conduct survey work in the study areas:

<b>Consultant</b>	<b>Address</b>	<b>Phone / Email</b>
David A. Savitz, PhD Professor and Chair	Department of Epidemiology, CB #7435 University of North Carolina School of Public Health Chapel Hill, North Carolina 27599-7400	919-966-7427 <a href="mailto:david_savitz@unc.edu">david_savitz@unc.edu</a>
Philip C. Singer, PhD Professor	Department of Environmental Sciences and Engineering, CB #7400 University of North Carolina School of Public Health Chapel Hill, NC 27599-7400	919-966-3865 <a href="mailto:phil_singer@unc.edu">phil_singer@unc.edu</a>
Katherine Hartmann, MD, PhD Assistant Professor	NC Program for Women's Health Research Sheps Center CB# 7590 Chapel Hill, NC 27599-7400	919-966-7928 <a href="mailto:khartman@med.unc.edu">khartman@med.unc.edu</a>
Howard Weinberg, D.Sc. Research Assistant Professor	Department of Environmental Sciences and Engineering CB# 7400 University of North Carolina School of Public Health Chapel Hill, NC 27599-7400	919-966-3859 <a href="mailto:howard_weinberg@unc.edu">howard_weinberg@unc.edu</a>
Irva Hertz-Picciotto, PhD Professor	Department of Epidemiology CB #7435 University of North Carolina School of Public Health Chapel Hill, NC 27599-7400	919-966-7445 <a href="mailto:ihp@unc.edu">ihp@unc.edu</a>
Christina Makarushka, MPH	Department of Epidemiology CB# 8050 University of North Carolina School of Public Health 137 E Franklin Street Suite 32 Room 3217 Chapel Hill NC 27514	919-966-6649 <a href="mailto:christina_makarushka@unc.edu">christina_makarushka@unc.edu</a>
Kirsten Waller, Ph.D.	13150 Mink Farm Road Thurmont, MD 21788	301-271-0767 <a href="mailto:KWDHS@aol.com">KWDHS@aol.com</a>
David Ozonoff, Ph.D.	Boston University School of Public Health Dept. of Environmental Health 715 Albany Street Boston, MA 02118	617-638-4620 <a href="mailto:dozonoff@bu.edu">dozonoff@bu.edu</a>

<b>Consultant</b>	<b>Address</b>	<b>Phone / Email</b>
Sherry G. Selevan, Ph.D.	US EPA NCEA/ORD/EPA (8623 D) Washington, DC 20460	202-564-3312 <a href="mailto:selevan.sherry@epa.gov">selevan.sherry@epa.gov</a>
Pauline Mendola, Ph.D.	US EPA HSD MD 58A Research Triangle Park, NC 27711	919-966-6953 <a href="mailto:mendola.pauline@epa.gov">mendola.pauline@epa.gov</a>
Charles Hertz, Ph.D. Manager	Laboratory/Technical Services Philadelphia Suburban Water Company 762 W Lancaster Ave Bryn Mawr, PA 19010-3489	610-525-1400 <a href="mailto:hertz@suburbanwater.com">hertz@suburbanwater.com</a>
Gary Amy, Ph.D.	University of Colorado at Boulder PO Box 428 Dept of Civil, Environ. & Architect. Eng. Boulder, CO 80309	303-492-6274 <a href="mailto:gamy@spot.colorado.edu">gamy@spot.colorado.edu</a>
Judith Klotz, DrPh	Cancer Epidemiology Services NJ Dept of Health and Senior Services PO Box 369 Trenton, NJ 08625-0369	609-588-3500 <a href="mailto:jklotz@doh.state.nj.us">jklotz@doh.state.nj.us</a>
LaTisha Griffin Data collection supervisor	Battelle Centers for Public Health Research and Evaluation 100 Capitola Drive, Suite 301 Durham, NC 27713	919-544-3717
Cathy Colvard Study leader	Battelle Centers for Public Health Research and Evaluation 100 Capitola Drive, Suite 301 Durham, NC 27713	919-544-3717

### **3. (d) Effects of Less Frequent Collection**

Not applicable; this is a one-time data collection activity for both components.

### **3. (e) General Guidelines**

This ICR conforms to OMB's general guidelines for the collection of information described in the *ICR Handbook*. The parent study has also been reviewed and approved by the University of North Carolina School of Public Health Institutional Review Board on Research Involving Human Subjects.

### **3. (f) Confidentiality**

All pregnancies will be assigned a unique patient identifier and confidentiality will be carefully protected. The local site manager will have access to personal identification information (name, home phone number and home address), since women need to be telephoned, we need to verify that their home receives water from the participating water utility, and there may be a visit to her home. The staff data entering the form which assigns her the unique coded identification number will have access to personal identifiers. The data manager will also have access to the data file with personal identifiers. All other study personnel will only have access to the coded identification number as part of the working data files. Working data will be stored on computers in secure data files available only to the University of North Carolina team members and members of EPA/NCEA. The UNC researchers have extensive experience in conducting surveys so that confidentiality is protected. Through these mechanisms, confidentiality of subjects who agree to participate in the survey is assured.

### **3. (g) Sensitive Questions**

The telephone questionnaire and the 24-hour recall do not include any questions regarding sexual behavior or attitudes, religious beliefs, or other matters usually considered private. In addition, response to all questions in the surveys is strictly voluntary.

## **Section 4. The Respondents and the Information Requested.**

### **4. (a) Respondents / SIC Codes**

The proposed information collection targets individuals (i.e. pregnant women) who are residents of Raleigh, NC, Memphis, TN and Galveston County, TX and currently enrolled in the ongoing parent study. For the telephone questionnaire and the 24-hour recall, respondents will be randomly selected at the time of the initial intake interview of the parent study and asked to participate. The subcontractor collecting the survey responses will make it clear that participation is voluntary. Monetary incentives are provided to all the volunteer participants included in this ICR.

### **4. (b) Information Requested**

#### *(i) Data Items, Including Record Keeping Requirements*

The full text of the telephone questionnaire and the 24-hour recall is attached at the end of this document and discussed in detail in Part B of this Supporting Statement. These surveys seek to gauge water usage and as such should not require respondents to search existing records or to reformat information to submit to the Agency. There will be no public record keeping activities under this ICR.

*(ii) Respondent Activities*

Respondents will be asked to answer a series of survey questions either by telephone questionnaire or 24-hour recalls.

Activities involved in the reliability component (via the telephone questionnaire):

- listen to short introduction of the survey and instructions for answering questions
- complete telephone interview

Activities involved in the validity component (via the 24-hour recall):

- read instructions
- complete three 24-hour recalls
- estimate typical water use activities such as dish washing, bathing, etc.
- estimate the amount of beverages consumed in the home and workplace

**Section 5. The Information Collected — Agency Activities, Collection Methodology and Information Management.**

**5. (a) Agency Activities**

The majority of the actual information collection activities performed under this ICR are the primary responsibility of the UNC cooperator. The main EPA activities are as follows;

- prepare and obtain OMB approval for ICR
- Management of Cooperative Agreement including a) review progress reports/budget expenditures and b) provide funds to cooperators on annual basis
- assist cooperator with the development of the 24-hour recall survey
- collaborate in the development of analytical strategies
- Contribute to analyses/review results
- Write reports/journal articles

The UNC cooperator has the primary responsibility to develop the surveys, facilitate and conduct the surveys, compile and store the data, analyze survey findings, and produce summary reports.

## **5. (b) Collection Methodology and Management**

In collecting and analyzing the information associated with this ICR, the University of North Carolina (under Cooperative Agreement No. CR828455-01-0) will follow a number of procedures for collection and management of survey data.

- Data quality will be ensured via adequate training and supervision of data collectors.
- Reliability of computer programs will be verified with test data prior to use.
- Computer data-coders will be adequately trained and supervised.
- Data input will be stored on both secured hard drives and on another medium such as floppy disk or CD ROM. Data shared across UNC investigators will be shared on an access-protected, dedicated website.
- Public access to the study's main findings will be made available via the Right From the Start website. Final reports will disclose only aggregated anonymous data.

## **5. (c) Small Entity Flexibility**

The proposed survey is targeted solely at pregnant women in Raleigh, NC, Memphis, TN, and Galveston County, TX, who have voluntarily enrolled in the ongoing parent study and who voluntarily agree to complete the additional questions from this ICR. No significant economic impact will be imposed on any respondent. Small entity flexibility is not applicable to this ICR.

## **5. (d) Collection Schedule**

Upon OMB approval, the information collection will be initiated. The University of North Carolina will complete the following tasks during a two-year time period following approval:

- (i) give the subcontractor the go-ahead for the final questionnaires (in month following OMB approval)
- (ii) recruitment of mothers during intake interviews for validity and reliability components (in month following OMB approval through date necessary for recruitment of 300 subjects each)
- (iii) distribution and collection of 24-hour recalls (in month 1 following OMB approval through date necessary for recruitment of 300 subjects)
- (iv) administration of telephone survey (in month 1 following OMB approval through date necessary for recruitment of 300 subjects)
- (v) phone follow-up (if needed) to non-respondents (throughout subject recruitment period)
- (vi) make summary tables and analyses available (approximately 2 years after OMB approval)

## Section 6. Estimating the Burden and Cost of the Collection.

### 6. (a) Respondent Burden

It is estimated that there will be 600 respondents in the two phases of the Reliability, Validity, and Variability in Behavior Determinants of Drinking Water Disinfection By-Product Exposure study. For the reliability component each respondent will spend approximately 15 minutes completing the telephone interview. For the validity component, each respondent will spend approximately 90 minutes (30 minutes each for 3 days) completing the 24-hour recalls. The estimated total response burden of 525 hours (Table 6.a). The burden estimates are based on findings from the water usage section of the participant's original interview in the parent study which is already underway. This information will be summarized in the required Federal Register notice. No third-party activities will be part of this one-time information collection. Note: The burden estimates for the surveys reflect a one-time expenditure, so they are equal to annual expenditures during the single year that the survey is conducted.

<b>Table 6.a Respondent Burden</b>			
<b>Survey Type</b>	<b>Estimated # of Respondents</b>	<b>Estimated Time (minutes)</b>	<b>Estimated Time (hours)</b>
Telephone Questionnaire	300	15 / respondent	75
24-Hour Recall	300	90 / respondent	450
<b>TOTAL</b>	600		525

### 6. (b) Respondent Costs

#### *(i) Labor Costs*

Wage estimates are based on the "Employer Cost for Employment Compensation" (Bureau of Labor and Statistics USDL 00-186, March 2000). Labor costs are estimated at \$21.16 per hour (average total compensation [inclusive of benefits] for all civilian workers). Burden activities include only a few steps: reading or listening to instructions, reading or listening to survey questions and responding to survey questions. The average cost per respondent to the telephone survey is \$5.40. The average cost per respondent for the three 24-hour recalls is \$32.40. The overall average cost per respondent is \$18.90 (Table 6.b.i)

<b>Table 6.b.i</b> <b>Respondent Costs</b>				
<b>Survey Type</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>	<b># of Respondents</b>	<b>Cost per Respondent</b>
Telephone Questionnaire	75	\$1,620.00	300	\$5.40
24-Hour Recall	450	\$9,720.00	300	\$32.40
<b>TOTAL</b>	525	\$11,340.00	600	\$18.90

*(ii) Capital and Operations and Maintenance Costs*

There are no capital and operations and maintenance costs associated with the respondent's participation.

*(iii) Capital / Start-up vs. Operating and Maintenance (O&M) Costs*

There are no capital/Start-up and operating and maintenance costs associated with the respondent's participation.

*(iv) Annualizing Capital Costs*

Not applicable. There are no capital costs.

**6. (c) Agency Burden and Cost**

Burden and cost estimates for the major Agency activities identified in section 5a above are displayed in table 6c.i. Based on the 2002 GS pay schedule for New York, EPA estimates an average hourly regional labor cost of \$63.19 for a GS13-7 health scientist and \$37.70 for a post-doctoral researcher. To derive hourly estimates, EPA divided the annual compensation estimate by 2,080 which is the number of hours in the Federal work year. EPA then multiplied the hourly rate by the standard government benefits multiplication factor of 1.6. The same procedure was followed to calculate the cost for post-doctoral researcher, using the annual salary rate provided by the ORISE post-doctoral program in the Federal government as the base.

We note again that the UNC cooperator has the primary responsibility to develop the surveys, facilitate and conduct the surveys, compile and store the data, analyze survey findings, and produce summary reports. This will be accomplished via extramural research funding of \$99,000/year for 3 years for a total cost of \$297,000. The major breakdown of budget costs as provided by the University of North Carolina is shown in Table 6.c.ii, also in this section.

<b>Table 6.c.i</b> <b>Annual Agency Burden Hours and Costs Hours/Cost per category</b>					
<b>Information Collection Activity</b>	<b>GS 13 Scientist \$63.19/hr</b>	<b>Post-Doctoral Researcher \$37.70/hr</b>	<b>Agency Hours/Year</b>	<b>GS 13 Scientist Cost/Year</b>	<b>Post-Doctoral Researcher Cost/Year</b>
1. Prepare ICR	40	60	100 (1 <sup>st</sup> year only)	2,527.60	2,262.00
2. Management of Cooperative Agreement					
a) review progress reports/budget expenditures	40	0	40	2,527.60	0.00
b) provide funds to cooperators on annual basis	40	0	40	2,527.60	0.00
3. Help develop 24 hr recall survey	20	40	60	1,263.80	1,508.00
4. Help develop analytical strategy	100	100	200	6,319.00	3,770.00
5. Contribute to analyses/review results	100	100	200	6,319.00	3,770.00
6. Write reports/ journal articles	500	600	1100	31,595.00	22,620.00
<b>TOTAL</b>	<b>840</b>	<b>900</b>	<b>1740</b>	<b>53,079.60</b>	<b>33,930.00</b>

**Table 6.3.ii**  
**UNC Cooperative Budget**

		Year 1		Total	Year 2		Total	Year 3		Total
Salary	Projection direction	2 hr/wk	\$8,288		2 hr/wk	\$8,615		2 hr/wk	\$8,956	
	Data collection	28 hr/wk	\$34,457		28 hr/wk	\$35,161		28 hr/wk	*\$32,648	
	Program ming/analysis	8 hr/wk	\$13,272		8 hr/wk	\$13,785		8 hr/wk	\$14,318	
				\$56,017			\$57,561			\$55,922
Consultant				\$3,000			\$1,500			\$3,000
Supplies				\$2,900			\$900			\$900
Travel				\$0			\$1,480			\$1,500
Other	Communication		\$300			\$600			\$719	
	Incentives		\$6,000			\$6,000			\$6,000	
				\$6,300			\$6,600			\$6,719
Total Direct Costs				\$68,217			\$68,041			\$68,041
Total Indirect Costs				\$30,784			\$30,959			\$30,959
<b>Total Cost</b>				\$99,000			\$99,000			\$99,000

\*Interviewer only used 10 months

#### 6. (d) Respondent Universe and Total Burden Hours and Costs

An estimated 600 respondents will voluntarily respond to the survey at a total burden of 525 hours and a total cost of \$11,340.00. Respondents will receive a monetary incentive (\$20.00 each) for their voluntary participation.

#### 6. (e) Bottom Line Burden Hours and Costs

##### *(i) Respondents Tally*

<b>Table 6.e.i</b> <b>Bottom Line Burden Hours and Costs for Respondents</b>			
<b>Survey Type</b>	<b># of Respondents</b>	<b>Total Burden Hours</b>	<b>Total Cost</b>
Telephone Questionnaire	300	75	\$1,620.00
24-Hour Recall	300	450	\$9,720.00
<b>TOTAL</b>	600	525	\$11,340.00

##### *(ii) Agency Tally*

<b>Table 6.e.ii</b> <b>Bottom Line Burden Hours and Costs for Agency</b>		
<b>Category</b>	<b>Total Annual Burden Hours</b>	<b>Total Annual Costs</b>
GS and post doctoral scientist salaries-research and administrative activities	1740	\$87,009.60
Extramural research dollars provided to University of North Carolina	Not applicable	\$99,000.00
<b>TOTAL</b>	1740	\$186,009.60

## **6. (f) Reasons for Change in Burden**

This is a new, one-time data collection activity, therefore, this section is not applicable.

## **6. (g) Burden Statement**

Exhibit 6.3 presents the average annual respondent burden for all surveys. The public reporting burden is estimated to average 45.75 minutes per respondent as a one-time-only burden for completion of the surveys. This estimate includes time for reviewing instructions, reading and/or listening, and responding to survey questions. There is no record-keeping burden for the study participants, so there is no additional reporting burden beyond completion of the survey instruments.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, or disclose or provide information to or for a Federal agency. This includes, the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information; processing and maintaining information; disclosing and providing information; adjusting the existing ways to comply with any previously applicable instructions and requirements; training personnel to be able to respond to a collection of information; searching data sources; completing and reviewing the collection of information; and transmitting or otherwise disclosing or reporting on the information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Send comments on the Agency's need for this information, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave NW, Washington DC, 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17<sup>th</sup> Street NW, Washington DC 20503, Attention: Desk Officer for EPA. Include the EPA ICR number.

## **PART B OF THE SUPPORTING STATEMENT**

### **Section 1. Survey Objectives, Key Variables, and Other Preliminaries.**

Little is known about the accuracy and the amount of variability in a wide range of self-reported water-related activities during pregnancy. The reliability component will allow for a measure of consistency in reporting of water usage at two different time periods. The validity component, through comparison of two reported different survey methods, will provide some insight into the utility of using questionnaire-based estimates of water usage. The 24-hour recall will also yield valuable information regarding the variability of water-related activities over time.

#### **1. (a) Survey Objectives**

Survey responses are designed to provide answers to the following questions:

- Question 1.** What is the mother's water source and has it changed during pregnancy?
- Question 2.** How much water do women consume and do these habits change during pregnancy?
- Question 3.** What percent of water consumption consists of bottled water (versus tap water) or filtered water?
- Question 4.** What percent of water consumption does filtered tap water (versus unfiltered tap water) constitute?
- Question 5.** How much exposure to water do women receive via other activities?

#### **1. (b) Key Variables**

Key variables for the telephone survey and 24-hour recall include water source, cold and hot water consumption, bottled water use, home filtration use, frequency and duration of bathing, showering, swimming, washing dishes, washing clothes. All of these factors influence a mother's potential exposure level. The survey instruments will help us quantify the between and within-person variability in these exposures, will decrease the uncertainties related to misclassification of the exposure variables, and enhance our ability to more clearly interpret the validity and accuracy of reported study findings.

Section 2d below describes why each question (and thus each key variable) is included so that the research hypotheses can be tested.

#### **1. (c) Statistical Approach**

The study base from which the participants are selected are all medium sized urban areas, with the following population figures: Raleigh, NC:420,000; Memphis, TN: 600,000; Galveston County, TX: 240,000. Therefore, a census approach would be expensive and impose an unnecessary burden on residents. An anecdotal approach has the disadvantage that it is not rigorous enough and cannot be generalized to other similar areas. A statistical survey approach,

however, can select a sample large enough to identify differences that are important for the target population, yet small enough to minimize the burden on respondents.

The cooperative agreement has two components. The reliability analysis will include a telephone survey of approximately 15 minutes administered by a subcontractor. The validity analysis will be based on three 24-hour recalls which will each take approximately 30 minutes to complete. The survey instruments are designed to enable pregnant women to report on water usage activities during pregnancy. We expect to recruit 300 participants for each component, 100 from each geographical region. Therefore, the final data set will have 600 subjects.

The anticipated survey results will provide data for summary tables and statistical analysis that are expected to meet the survey objectives listed in Section 1a of Part B of this Supporting Statement.

#### **1. (d) Feasibility**

Respondents are not expected to face obstacles in completing the survey. Several steps have been taken to facilitate response. The instructions will stress that all of the questions ask about their specific water usage. Pretesting the questionnaires have ensured that respondents understand the words used and can answer the questions asked. The relatively few questions of fact should be quite straight-forward (e.g., How many glasses of bottled water do you usually drink per day? How often do you shower at home? How many minutes do you usually spend actually in the shower?).

Sufficient funds are available to complete the survey as designed. In the absence of sufficient funds, the sample size might have to be reduced, diminishing the ability to detect variability across these populations. Financial incentives will be offered to help ensure a sufficient number of participants.

This survey is being conducted as part of the cooperative agreement with the University of North Carolina and is not related to any rule-making activity at EPA. As such, the information does not face a particular deadline for specific decisions (aside from input for deciding among potential research priorities). However, the cooperator must show significant progress on an annual basis, so data collection must proceed in a timely fashion. The UNC team has demonstrated its ability to provide output in a timely manner.

## Section 2. Survey Design.

### 2. (a) Target Population and Coverage

The target population includes pregnant women served by one of three public water utilities in Raleigh, NC, Memphis, TN or Galveston County, TX. For the parent study, eligible residents are being recruited from family planning clinics, obstetric/gynecology offices, prenatal clinics, pharmacies and the community at large. The coverage for the reliability and validity components includes a random sample of 10 % of the eligible participants from the cohort (n=300 for each component). This coverage group will satisfy our information needs because they comprise a geographically-representative sample of the study population and will already be familiar with the questionnaire procedures prior to completion of the reliability and validity components.

### 2. (b) Sample Design

#### (i) Sampling Frames

The sampling frame for our survey will consist of all eligible pregnant women from the parent study. We will ensure confidentiality through the mechanisms described in Section 3f of Part A of this Supporting Statement.

#### (ii) Sample Size

The decision regarding sample size for both the validity and reliability studies involves reconciling the desire for statistical precision in measuring the associations of interest and the costs and effort required to recruit participants for this component of the study. We focused on the Pearson correlation coefficient as a simple measure of reliability (i.e., the correlation between assessment at time 1 and time 2) and of validity (i.e., the correlation between indices of exposure based on the 24-hour recall versus the questionnaire). Using Fisher's transformation (Rosner, B. *Fundamentals of Biostatistics*. 1982. Boston: Duxbury Press) to approximate the 95% confidence intervals around estimates of the correlation coefficient, we calculated confidence intervals for correlation coefficients of 0.40 and 0.60 for three different sample sizes (n=50, 100 or 200).

	Sample Size		
	<u>50</u>	<u>100</u>	<u>200</u>
<b>r=0.40</b>	0.14-0.61	0.22-0.55	0.28-0.51
<b>r=0.60</b>	0.39-0.75	0.46-0.71	0.50-0.68

Based on these estimates, 100 women from each region were determined to be the appropriate sample size for both the reliability and validity components. The minimal precision gained by increasing the sample to 200 hundred women for each region (shown above) was determined not to be a cost-effective use of limited resources. In addition to analyzing the

recruited women in the aggregate, we expect to analyze subgroups that are defined by tap water consumption, for example, and will want to calculate measures of agreement across study locations. By seeking a total of 300 women for each component, we would anticipate having reasonable power to estimate reliability and validity in such subsets of study participants. Relative to the small number of volunteers in previous water usage studies, the present study would be a major advancement.

*(iii) Stratification Variables*

Not applicable.

*(iv) Sampling Method*

Participants will be randomly sampled from all eligible subjects from the parent study.

The results should be generalizable to pregnant women across different geographical regions and socioeconomic levels. For purposes of this study, the representativeness of our sample of pregnant women is less crucial than meeting our objectives of quantifying the amount of variability within these populations and evaluating the accuracy of our measurements. However, we expect that the results for residents of Raleigh, Memphis, and Galveston County would be applicable to other areas.

*(v) Multi-stage Sampling*

Not applicable.

**2. (c) Precision Requirements**

*(i) Precision Targets*

Ninety-five percent confidence intervals will be determined for the target variables. An example of one of the target variables that will be queried is overall water consumption. While estimates of water consumption exist in the literature, we will be able to estimate the validity of two methods of measurement (questionnaire and 24-hour recall) in pregnant women with a great deal of precision. As noted in Section 2b.ii of Part B of this Supporting Statement, Pearson correlation coefficient estimates based on sample size calculations indicate very precise confidence intervals will result from the large number of respondents. This level of precision should prove satisfactory for our decision-making needs.

## *(ii) Nonsampling Error*

If non-respondents have significantly different activities compared with respondents, the survey may not be representative of all sub-populations. We will have background information on the non-responders to compare with those who complete the reliability and validity components. However, there is no expectation that these research results could not be generalized to other populations. We do not expect any biases to result from the selection of participants, since it will be based on a random sample of the population irrespective of water usage and pregnancy outcome. The findings but also should unbiased due to extensive training and standardized interviewing protocol.

As described in Section 2a two different groups of 300 women will be randomly selected from the study population for both the reliability and variability components. Not only will this make the overall interview burden tolerable, it will reduce the potential for distorting the reliability data that might arise from extra attention to water use created by the variability surveys. In addition, UNC has a record of achieving high response rates, partly by designing questionnaires that respondents find appealing and providing financial incentives to participants.

## **2. (d) Questionnaire Design**

The telephone questionnaire and 24-hour recalls have been designed to minimize biases by making the questions straightforward, unambiguous, and arranged logically. As described in Section 3 below, the questionnaire has been pilot tested to ensure that respondents understand the questions and can respond appropriately. In the description below, each question or group of questions is linked to at least one Survey Objective listed in Part B, Section 1a. Recall that the survey objectives are listed as questions. Copies of the questionnaire and 24-hour recall are appended to this Supporting Statement.

### **Telephone Questionnaire**

All of the questions in the telephone survey are pre-coded which helps ensure the accuracy of the instrument. For the qualitative responses we attempted to minimize respondent burden by providing a choice of possible answers (yes/no or multiple choice categories). For the daily water consumption and time spent for a variety of activities questions, specific quantities are queried. For these questions, the interviewer offers guidance as to the size of the containers used. For example, “Are those glasses usually small like a juice glass, about 4-10 oz; medium like a water glass, about 10-12 oz; or large like a giant size drink at the movies/Fast food, about 22-34 oz?”. Questions A5, C1a, C1b, and C2a-c are included in order to verify respondent identity and to confirm the appropriate mailing address for disbursement of the financial incentive following survey completion. Question B6 is an instructional reminder to the respondents to answer the questions keeping in mind that the water usage responses are for a “typical week”.

A group of questions will enable answering Objective 1. Questions B1a, B1b, B1c, B2 and B5 ensures that the respondent has not moved during study enrollment. Question B4 asks about the source of tap water at their present address. If the respondent has moved, questions B2-B4 ask respondents to list the addresses, source water and length of residence for each other location.

A group of questions will enable answering Objective 2. Questions B7a-b (home and work), B9a-b (work), and B11a-b (home) ask about the amount (i.e. how many glasses and the size of glass) of cold tap water consumed. Questions B8a-b (home and work), B10a-b (work), and B12a-b (home) ask about the amount (i.e. how many glasses and the size of glass) of hot tap water consumed.

Questions B13a-c are linked to Objective 3. Question B13a specifically asks “how much of all the water you drank was bottled water”. Similar to the tap water usage section, Questions B13b-c ask about the amount (i.e. how many glasses and the size of glass) of bottled water consumed. Question B13d asks for the name of the brand of bottled water typically purchased.

Questions B14-B21 will help determine the influence of home filtration techniques addressed in Objective 4. Questions B18a and B19a ask about the amount of filtered tap water consumed and cooked with at home. Question B14 addresses whether tap water from the home is filtered at any time. If it is, Questions B15 and B17a specifies whether the system covered the entire house or specific locations such as the showerhead. Questions B17b, B18c and B19c asks for brand names of filters used for the entire house, showerheads and tap water. For residential tap water treatment, the respondents will be asked whether the filters used were at the faucet, part of the refrigerator, or part of a filtering pitcher (Question B18b). Frequency of filtration replacement will be queried in questions B17c, B18d and B20d. Consumption of filtered water outside of the home is addressed in Question B20a. Type, brand and frequency of filter replacement are addressed Questions B20b-d. Question B21 asks study participants what prompts filter replacement at home.

Objective 5 is addressed in Questions B22a-B29c. Frequency and duration of showering is addressed in Question B22a and B22b. Questions B22c and B22d asks about the time spent in the bathroom with the door closed before (with the water running) and after showering. Respondents are also asked about the frequency and duration of bathing themselves (Question B23a, B23c) and children (Question B24a B24b). Time spent in the enclosed bathroom before (with the water running) and afterward is dealt with in Questions B23d and B23e for self bathing and Questions B24c and B24d for bathing children. Questions B23b asks about level of water used in the tub. Participants will be also be asked about the frequency (Questions B25a, B26a) and duration (Questions B25b, B26b) of washing dishes and clothes by hand. Modification of exposure by glove usage during the washing of dishes and clothes will be asked in Questions B25c and B26c. Frequency and duration of swimming is addressed in Questions B27a-B27b (total pool use) and Questions B28a-B28b (indoor pool use only). Questions 28c and 29c ask the respondent whether chlorine was used to disinfect the pool most frequented. Hot tub and jacuzzi

usage (frequency and duration) is queried in Questions 30a-b, while Question 30c asks whether chlorine was used to disinfect the hot tub or jacuzzi most frequented.

## **24-Hour Recall**

Part I of the 24-hour recall asks the respondent to record the amount and type of all beverages consumed. This corresponds with Objectives 2-4 since they will be asked to record tap, bottled and filtered water consumption. Parts II-IV primarily focus on Objective 5 which measures the impact of other water-related activities that may influence exposure. These include: bathing, showering, washing dishes, washing clothes, washing children, and pool/hot tub/jacuzzi use. Objective 5 is also addressed in Part II through recording of ventilation measures (fan, door and window) used during bathing and showering, the percentage of body immersed while bathing, and the time spent in the bathroom before and after bath or shower. Additional information recorded on the 24-hour recall that addresses exposure modification include the proportion of body immersed while bathing (Part II), type of pool/hot tub/jacuzzi used (Part III), and glove usage during washing of dishes, clothes and children (Part IV). Entries regarding location of water usage (found in Parts I-III) will address both Objective 5 and Objective 1.

## **Section 3. Pretests and Pilot Tests.**

### **Telephone Questionnaire**

The water usage questionnaire for the validity component utilizes a subset of questions from the main questionnaire of the parent study. The main questionnaire was piloted at prenatal clinics in North Carolina by the staff at the Battelle Centers for Public Health.

During pilot interviews, interviewers focused on the following aspects of the questionnaire:

- length of interview
- clarity of questions: could they be read easily by the interviewer and understood by the respondent?
- did questions result in the type of information desired by researchers?
- could respondents recall information for the time frames requested?
- did certain questions make the respondent uncomfortable?
- what issues needed to be addressed in interviewer training
- what special interviewer instructions needed to be added to the computer screen?

Following the pilot interviews, issues and questions were brought to the attention of researchers in a written report. The researchers evaluated these issues and modified the questionnaire as appropriate.

## **24-Hour Recall**

The 24-hour recall is a standard research tool which consists of diary-type entries of water usage and contact during the day. A series of 24-hour recalls is required to provide a suitable benchmark against which water usage questionnaires can be validated. The 24-hour recall is appended to this Supporting Statement and is similar to those pre-tested in a previous study by a member of the UNC research team (Savitz). An instruction sheet is also attached and will help guide participants through the use of the 24-hour recall.

## **Section 4. Collection Methods and Follow-up.**

### **4. (a) Collection Methods**

The telephone interview and self-administered 24-hour recalls were chosen to minimize respondent burden. Because the telephone data will be collected by a reputable survey firm (Battelle), the interviewers already will have been screened to be appropriate in their interviewing skills. Prior to administering the survey, the interviewers will receive project-specific training which covers the background of the parent study, the project-specific protocol, and the questionnaire. Each interviewer must also complete a certification (mock) interview with an experienced trainer. This certification interview must demonstrate the interviewer's knowledge of the questionnaire and correct project protocol.

Battelle supervisors monitor 10% of interviews to ensure that respondent answers are coded correctly and proper project protocol is used. During the monitoring process, supervisors can observe the interviewer's computer screen from a remote location and listen to the conversation between the interviewer and the respondent. The interviewer is unaware that she is being monitored. The supervisor evaluates the interview based on a standard set of criteria. Feedback is provided to the interviewer immediately.

### **4. (b) Survey Responses and Follow-up**

The target response rate for this research is eighty percent. Based on previous experience, it is extremely challenging to obtain the degree of cooperation required for repeated interviews and financial incentives are effective in enhancing the completeness of response. The UNC research team has a reputation for achieving high response rates in previous reproductive studies. For those women who agree to participate in the validation component, we will generate at the time of enrollment a random series of three days, two weekdays and one weekend, for the period between enrollment and the 20-week follow-up interview. In order to avoid sensitizing women to planned ascertainment and possibly distort their water use, we will call in the evening on those selected days. Because they may not be reachable on the exact days desired, the computerized selection algorithm will also provide contingency plans for alternative assessment dates. Again, the goal is to have information from three randomly chosen days between the interviews. For the reliability component, Battelle interviewers will make several attempts

during different times of day to reach the respondent. If these attempts are unsuccessful, another randomly selected participant will be selected for the study.

## **Section 5. Analyzing and Reporting Survey Results.**

### **5. (a) Data Preparation**

The UNC research team will be in charge of data entry and management prior to the analysis. Standard data entry procedures will be followed by the trained staff including double entry of the data and the use of a computer edit program. The data manager will also monitor the dataset for internal consistency. If data entry errors are detected they will be corrected based on data from the original surveys. We do not expect large amounts of missing data with the telephone questionnaires since they are being administered by a professional interviewing staff. Completeness of the 24-hour recalls will be evaluated on a case-by-case basis by the data manager. Incomplete surveys may result in their exclusion from the data analysis.

### **5. (b) Analysis**

For continuous measures of exposure, Pearson correlation coefficients will be calculated as well as intraclass correlation coefficients and 95% confidence intervals using analysis of variance (Fleiss PE, Shrout JL. "Intraclass Correlations: Uses in Assessing Rater Reliability." *Psychological Bulletin*, 1979, Volume 86, Number 2, pages 420-428). Two-way analysis of variance models take into account the potential for differences due to the mode of data collection at the two times of evaluation (Armstrong et al., 1992). For categorical variables, we will characterize the percent agreement by summing the persons who are on the diagonal reflecting exact agreement in the matrix of scores on the first and second interview, along with 95% confidence intervals (Chinn S, Burney PG. "On Measuring Repeatability of Data from Self-administered Questionnaires." *International Journal of Epidemiology*, 1987, Volume 16, Number 1, pages 121-127). Kappa coefficients with 95% confidence intervals will be used to measure agreement beyond that expected by chance (Maclure M, Willett WC. "Misinterpretation and Misuse of the Kappa Statistic." *American Journal of Epidemiology*, 1987, Volume 126, Number 2, pages 161-169).

### **Data Presentation**

This data collection does not involve simple replication of analyses with familiar measures. So meaningful table shells cannot be designed until we know what sorts of scales emerge from the data analysis. Nevertheless, we shall report all frequencies in a straightforward manner, thereby informing readers as to the validity, reliability and variability of behavioral determinants of water usage. We will report distributions, not just means, so readers can assess the variability of measurements.

### **5. (c) Reporting Results**

The data analysis will be described in papers prepared for submission to peer-reviewed journals. These manuscripts will be made available to government (and other) reviewers. Summaries will also be prepared in a less technical format, for use by the participants and any other interested parties. The intent is to write both the technical and non-technical summaries (plus presentation materials) so that they demonstrate the potential usefulness of the data that was collected via these surveys.

As an additional safeguard to confidentiality (and to encourage a high response rate), the UNC research team does not plan to provide agency personnel and the public with direct access to the data base. However, they will have direct access to both technical and non-technical summaries and analyses, especially through the Right from the Start website (<http://www.rightfromthestart.unc.edu>).

**ATTACHMENT 1:**  
**24-Hour Recall and Instruction Sheet**

Dear Study Participant:

Thank you for agreeing to participate in the Right From the Start Study. This project is funded by the American Water Works Association Research Foundation and will examine the impact of different behaviors and exposures on reproductive health. The current survey focuses on water usage and will be used as part of a cooperative agreement between the University of North Carolina and the Environmental Protection Agency (CR828455-01). The public reporting and recordkeeping burden for this collection is estimated to average 30 minutes per survey. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed survey to this address.

Please remember that participation in this survey is voluntary and all information you provide is strictly confidential. No information provided to us will be linked to you specifically because answers from all women who participate in the study, up to 3000 women, will be pooled together. In addition, your name will never be used in any report about the study. We have provided detailed instructions with examples on the following two sheets. We will mail you a \$10 check upon receipt of each completed survey. If at any time you have any questions or concerns, please do not hesitate to contact the study staff at Right From the Start. The toll-free telephone number is 1-866-346-2684.

Thank you,

Dr. David Savitz  
The University of North Carolina  
Department of Epidemiology  
School of Public Health-CB# 7435  
Chapel Hill North Carolina 27599-7400

Please provide your name, current address, along with the date and time you began the survey. For each section, please report activities during the last 24 hours.

**Part I: Water/Beverage Consumption**

1. Write in the approximate time and circle AM or PM to indicate when water or any other beverage was consumed.
2. Specify the name of the drink. Brand names may be used.
3. If water was consumed or used to make the beverage, circle Tap if the beverage came directly from tap water or was made with tap water (e.g. frozen juice). Circle Bottled if bottled water was consumed or used to make the beverage (Do not circle either choice if the beverage you listed was soda/pop or canned or bottled juices).
4. Circle Yes if water was filtered at the faucet, through the refrigerator, or through a filtering pitcher (e.g. Britta filter). Circle No if water was not filtered.
5. Circle Home, Work, or write in the name of the community or city where the water or beverage was obtained.
6. Indicate the amount of drink consumed in ounces.
7. Circle either Hot or Cold for each drink consumed.

**EXAMPLE:**

Time	Name of Beverage	Source of Water or Beverage	Filtered?	Location	Amount (in Ounces)	Hot/Cold
8 : 30 AM/PM	Hot Tea	Tap/Bottled	Yes/No	Home/Work Other _____	10	Hot/Cold

**Part II: Bathing/Showering Habits**

1. Write in the approximate time and circle AM or PM to indicate when the bath or shower took place.
2. Circle Bath or Shower.
3. Circle Home, Work, or write in the name of the community or city where the bath or shower took place.
4. Write in the approximate duration in minutes of the bath or shower.
5. Circle Yes or No to indicate whether there was any fan in use during the bath/shower.
6. Circle Window, Door or Both if the bathroom window or door were open during the bath/ shower.
7. Write in the approximate duration in minutes you spent before the bath/shower with the bathroom door shut and the water running.
8. Write in the approximate duration in minutes you spent after the bath/shower with the bathroom door shut.
9. (For bathers only) Circle the proportion that approximates the amount of body immersed while bathing.

**EXAMPLE:**

Time	Bath/Shower	Location	Bath/Shower Duration (minutes)	Was the Fan On?	Open Door/ Window?	# Min. Spent with Door Shut Before After	Amount of Body Immersed
8 : 00 AM/PM	Bath/Shower	Home/Work Other _____	12	Yes/No	None/Window/ Door/Both	1 0	>1/2 1/2 1/4

### **Part III: Swimming Pool/Hot Tub/Jacuzzi Use**

1. Write in the approximate time and circle AM or PM to indicate when you swam or used a hot tub/jacuzzi.
2. Write in the name of the place where you swam or used a hot tub/jacuzzi.
3. Circle Swimming or Hot Tub/Jacuzzi to indicate the type of activity you participated in.
4. Circle Outdoor if the pool/hot tub/jacuzzi was outdoor or Indoor if the pool/hot tub/jacuzzi was either indoor or in an enclosed area.
5. Write in the approximate duration in minutes for each activity.

**EXAMPLE:**

Time	Location	Type of Activity	Type of Pool/ Hot Tub/Jacuzzi	Duration (minutes)
<u>8</u> : <u>00</u> AM/PM	<u>YMCA</u>	<b>Swimming/</b> Hot Tub or Jacuzzi	<b>Indoor/Outdoor</b>	<u>25</u>

## Part IV: Other Water-Related Activities

1. Circle all the items which correspond to tasks you performed during the day which last for 15 minutes or longer. If the task is not already listed, you may write it in the space provided.
2. Write in the number of times you conducted this task during the day.
3. Write in the approximate duration in minutes for each task.
4. Circle Yes if gloves were used or No if they were not used for the activities you listed.

**EXAMPLE:**

Activity (greater than 15 minutes)	Number of Times	Total Duration (minutes)	Gloves Used?
Bathing Children	<u>0</u>	<u>0</u>	Yes/No
Hand Dishwashing	<u>2</u>	<u>30</u>	Yes/ <b>No</b>
Hand Clotheswashing	<u>0</u>	<u>0</u>	Yes/No
Other	<u>0</u>	<u>0</u>	Yes/No

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_

OMB Control No: 2080-XXXX  
 Expiration date xx/xx/xx

Date: \_\_\_\_\_  
 Time survey started: \_\_\_\_ : \_\_\_\_ A.M. P.M. [circle one]

ID#: \_\_\_\_\_[office use only]

**Part I: Water/Beverage Consumption**

Time	Name of Beverage	Source of Water or Beverage	Filtered Water?	Location	Amount (in Ounces)	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold
____ : ____ AM/PM	_____	Tap/Bottled	Yes/No	Home/Work Other _____	_____	Hot/Cold

## Part II: Bathing/Showering Habits

Time	Bath/Shower	Location	Bath/Shower Duration (min.)	Was the Fan On?	Was the Window or Door Open?	# Min. Spent with Door Shut Before	After	Amount of Body Immersed
___ : ___ AM/PM	Bath/Shower	Home/Work Other _____	_____	Yes/No	Window/ Door/Both	_____	_____	>1/2 1/2 1/4
___ : ___ AM/PM	Bath/Shower	Home/Work Other _____	_____	Yes/No	Window/ Door/Both	_____	_____	>1/2 1/2 1/4
___ : ___ AM/PM	Bath/Shower	Home/Work Other _____	_____	Yes/No	Window/ Door/Both	_____	_____	>1/2 1/2 1/4
___ : ___ AM/PM	Bath/Shower	Home/Work Other _____	_____	Yes/No	Window/ Door/Both	_____	_____	>1/2 1/2 1/4

## Part III: Swimming Pool/Hot Tub/Jacuzzi Use

Time	Location	Type of Activity	Type of Pool/ Hot Tub/Jacuzzi	Duration (minutes)
___ : ___ AM/PM	_____	Swimming/ Hot Tub or Jacuzzi	Indoor/Outdoor	_____
___ : ___ AM/PM	_____	Swimming/ Hot Tub or Jacuzzi	Indoor/Outdoor	_____
___ : ___ AM/PM	_____	Swimming/ Hot Tub or Jacuzzi	Indoor/Outdoor	_____

## Part IV: Other Water-Related Activities

Activity	Number of Times	Total Duration (minutes)	Gloves Used?
Bathing Children	_____	_____	Yes/No
Hand Dishwashing	_____	_____	Yes/No
Hand Clotheswashing	_____	_____	Yes/No
Other _____	_____	_____	Yes/No

Time survey completed: \_\_\_ : \_\_\_ A.M. P.M. [circle one]

**ATTACHMENT 2:**  
**Telephone Questionnaire**

Dear Study Participant:

Thank you agreeing to participate in the Right From the Start Study. This project is funded by the American Water Works Association Research Foundation and will examine the impact of different behaviors and exposures on reproductive health. The current survey focuses on water usage and is part of a cooperative agreement between the University of North Carolina and the Environmental Protection Agency (CR828455-01). We will provide instructions for completion of this telephone questionnaire before we begin and a \$10 check will be mailed to you following its completion. The public reporting and recordkeeping burden for this one-time collection is estimated to average 15 minutes. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

You can send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence.

Please remember that participation in this survey is voluntary and all information you provide is strictly confidential. No information provided to us will be linked to you specifically because answers from all women who participate in the study, up to 3000 women, will be pooled together. In addition, your name will never be used in any report about the study. If at any time you have any questions or concerns, please do not hesitate to contact the study staff at Right From the Start. The toll-free telephone number is 1-866-346-2684.

Thank you,

Dr. David Savitz  
The University of North Carolina  
Department of Epidemiology  
School of Public Health-CB# 7435  
Chapel Hill North Carolina 27599-7400

# Right from the Start

## Water Usage Questionnaire (Reliability Component)

Department of Epidemiology  
Department of Environmental Sciences and Engineering  
School of Public Health  
The University of North Carolina  
CB# 7400  
Chapel Hill North Carolina 27599-7400

This project is funded by the American Water Works Association Research Foundation. For more information, contact the principal investigator, Dr. David Savitz, 919-966-7427, or the project director, Christina Makarushka, 919-966-6649, both at the University of North Carolina School of Public Health, Department of Epidemiology.

June 22, 2001

# Table of contents

<b>Section A Preliminary information and introduction to the study</b>	<b>1</b>
<u>Introduction</u>	1
<b>Section B Water exposure</b>	<b>3</b>
<u>Total cold tap water use[home and work]</u>	4
<u>Total hot tap water use[home and work]</u>	4
<u>Cold tap water use at work</u>	5
<u>Hot tap water use at work</u>	5
<u>Cold tap water use at home</u>	6
<u>Hot tap water use at home</u>	6
<u>Bottled water</u>	7
<u>Filtering</u>	8
<u>Showering</u>	10
<u>Bathing</u>	10
<u>Children</u>	11
<u>Dishes</u>	11
<u>Clothes</u>	12
<u>Swimming</u>	12
<u>Hot tub</u>	13
<b>Section C Closing</b>	<b>14</b>
<u>Interviewer Remarks</u>	15

## Section A Study Introduction

- A1. Participant ID: \_\_\_\_\_
- A2. Interviewer ID: \_\_\_\_\_
- A3. Date of interview: month: \_\_\_\_\_ day: \_\_\_\_\_ year: \_\_\_\_\_
- A4. Time interview started: \_\_\_\_ : \_\_\_\_ A.M. P.M. [circle one]

### *Introduction*

Hello, my name is [\_\_\_\_\_]. May I speak with [\_\_\_\_\_]? I'm calling from Right from the Start.

**If she is not there:** Ask for a time when you can call back.

Day \_\_\_\_\_ Time \_\_\_\_\_

I'm calling to complete the follow-up telephone interview for the Right from the Start study and as part of a cooperative agreement between the University of North Carolina and the Environmental Protection Agency. This interview will take about 15 minutes. We will mail you a check for \$10 for completing this interview. Do you have time right now?

**If yes:** *[Continue with interview.]* We really appreciate your willingness to help even though this may be difficult for you to do.

**If no:** Ask for a better time to call back in the next few days.

Day \_\_\_\_\_ Time \_\_\_\_\_

**A5. Before we start, I would like to confirm your date of birth to make sure I have the correct record. What is it?**

\_\_\_\_\_ DOB *[does it match the DOB from the screening interview?]*

**[When she is ready to begin]**

I'd also like to remind you that:

- (d) Everything you tell me is confidential and participation in this questionnaire is strictly voluntary.
- (e) No information you give us will be linked to you specifically because answers from all women who participate in the study will be pooled together. Your name will never be used in any report about the study.
- (f) If at any time you don't understand a question, please let me know and I'll try to make it clearer.
- (g) There are no right or wrong answers, we're really interested in what you've experienced.
- (h) You don't have to answer any question you feel uncomfortable answering, but we hope that you will feel comfortable answering all our questions.
- (i) My supervisor may listen to this interview to make sure I'm doing the best job possible.

**A6. Do you have any questions for me at this point?**

**If yes:** Answer the questions or if you cannot answer her questions, refer her to Right from the Start's toll-free telephone number 1-866-346-2684.

**If no:** Continue

## Section B Water exposure

The next set of questions is about your use of water for drinking, cooking, cleaning, showering and swimming. Water use in pregnancy and its effect on pregnancy has not yet been studied thoroughly. I'm first going to ask about the places you have lived since your first interview on \_\_\_\_\_ [date].

**B1a. Do you currently live at [address from screening interview]?**

yes → skip to B2.                      no                      don't know/refused

**B1b. Please tell me the street address, city and state [where you currently live/of your next most recent residence].** *[If she doesn't give us her address, we will not be able to mail her check to her.]*

Don't know

**B1c. Would you tell me the city you currently live in?**

**B2. Have you lived at this residence for more than 4 months?**

Yes → skip to B7a. if B1a is yes, otherwise, continue with B4.

No

**B3. When did you move to this address?**

month/day/year

**B4. [Is/was] the source of your tap water at \_\_\_\_\_ [street address], that is the water that comes out of your faucets, from a private well or from the public water supplier [your town or city]?**

If B2 = yes, → B6.

**B5. How many addresses other than your current address have you lived at since [date 4 months ago]?** *[only her primary residences ie. where she spends most of her time. No vacation spots unless she spends a part of the year at this residence at which time it is her primary residence.]*

\_\_\_\_\_ # addresses

*Ask B1b, B3, and B4 for each additional address where the woman has lived in the last 4 months.*

	Residence #1	Residence #2	Residence #3
<b>B1a.</b>	yes → skip to B2. No		
<b>B1b. Add ress</b>	Street: Apt. or lot#. City, State, Zip code	Street: Apt. or lot#. City, State, Zip code	Street: Apt. or lot#. City, State, Zip code
<b>B2.</b>	Yes → B4. if B1a. = no Yes → B6. if B1a = yes No	yes no	yes no
<b>B3.</b>	___/___/___ mm/dy/yr	___/___/___ mm/dy/yr	___/___/___ mm/dy/yr
<b>B4.</b>	private well city/town	private well city/town	private well city/town

**B6. Was this past week a typical week for you, meaning that you weren't on vacation or there wasn't anything unusual that would affect your water use?** *[auto fill from Ca., if no just remind respondent to think of a typical week and if yes skip this question]*

Yes → For the following questions about water use, please think about what you drank over the past week when answering what you typically drink in a day.

No → A quick reminder, since last week was not typical for you, for all the following questions please think about a week that you would consider a typical week for you.

*Total cold tap water use[home and work]*

Now, I'm going to ask you questions about how much cold tap water you typically drink each day. For these questions, include both filtered and unfiltered water, from your home and work place [if she works]. Also include all cold drinks made from that tap water such as powdered drinks. Do not include bottled or canned drinks.

*[interviewer notes: include water from the tap, refrigerator spigot or refrigerated water fountain. Cold drinks include instant iced tea but not brewed, and drinks from concentrate. No bottled water, no sodas, no canned or bottled juices. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks.]*

<p><b>B7a. How many glasses of tap water, including cold drinks made with tap water, do you usually drink per day?</b></p>	<p>___ # of glasses per day → if 0 skip to B8a.          ___ &lt;1 per day → B8a.          Don't know/refused → to B8a</p>
<p><b>B7b. Are those glasses usually small like a juice glass, about 4-10oz; medium like a water glass, about 12-20; or large like a giant size drink at the movies/Fast food, about 22-34oz?</b></p>	<p>Sm          Med          Lg          Other: _____          Don't know/refused</p>

*Total hot tap water use[home and work]*

Next, I'm going to ask you questions about how many hot drinks made with tap water you typically drink each day. For these questions, include drinks made with tap water from your home and your work [if she works]. *[Hot water means that she boiled the water on the stove or in a microwave to get it hot. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks.]*

<p><b>B8a. How many cups of hot drinks made from tap water, such as coffee, tea including brewed iced tea, hot chocolate or cup-a-soups, do you usually drink per day?</b></p>	<p>___ # of cups per day → if 0 skip to B9a.          ___ &lt;1 per day → B9a.          DK/refused → to B9a.</p>
--	--

<b>B8b. Are those cups usually small like a tea cup, about 4-10 oz; medium like a coffee mug, about 12-14oz; or large like an travel mug or oversized coffee mug, about 16-24oz?</b>	Sm Med Lg Other: specify _____ don't know/refused
--	---

*Cold tap water use at work*

Now, I'm going to ask you questions about how much cold tap water you typically drink each day at work. For these questions, include both filtered and unfiltered water, from your work place. Also include all cold drinks made from that tap water such as powdered drinks. Do not include bottled or canned drinks.

*[interviewer notes: include water from the tap, refrigerator spigot or refrigerated water fountain. Cold drinks include instant iced tea but not brewed, and drinks from concentrate. No bottled water, no sodas, no canned or bottled juices. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks.]*

<b>B9a. How many glasses of water from your office tap do you usually drink per day?</b>	____ # of glasses per day → if 0 skip to B10a. ____ <1 per day → B10a. OK/refused → to B10a.
<b>B9b. Are those glasses usually small like a juice glass, about 4-10oz; medium like a water glass, about 12-20; or large like a giant size drink at the movies/Fast food, about 22-34oz?</b>	Sm Med Lg Other: specify _____ Don't know/refused

*Hot tap water use at work*

Next I'm going to ask you questions about how many hot drinks made with tap water from work you typically drink per day. *[Hot water means that she boiled the water on the stove or in a microwave to get it hot. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks. Include both filtered and unfiltered tap water.]*

<b>B10a. How many cups of hot drinks made from office tap water, such as coffee, tea including brewed iced tea, hot chocolate or cup-a-soups, do you usually drink per day?</b>	____ # of cups per day → if 0 skip to B11a. ____ <1 per day → B11a. DK/refused → to B11a.
---	---

<b>B10b. Are those cups usually small like a tea cup, about 4-10 oz; medium like a coffee mug, about 12-14oz; or large like an travel mug or oversized coffee mug, about 16-24oz?</b>	Sm Med Lg Other: specify _____ don't know/refused
---	---

*Cold tap water use at home*

Now, I'm going to ask you questions about how much cold tap water you typically drink per day at home. For these questions, include both filtered and unfiltered water. Also include all cold drinks made from that tap water such as powdered drinks. If you bring tap water from home to work, or other places, also include that water. Do not include bottled or canned drinks.

*[interviewer notes: include water from the tap, refrigerator spigot or refrigerated water fountain. Cold drinks include instant iced tea but not brewed, and drinks from concentrate. No bottled water, no sodas, no canned or bottled juices. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks.]*

<b>B11a. How many glasses of water from your home tap do you usually drink per day?</b>	____ # of glasses per day → if 0 skip to B12a. ____ <1 per day → B12a. DK/refused → to B12a.
<b>B11b. Are those glasses usually small like a juice glass, about 4-10oz; medium like a water glass, about 12-20; or large like a giant size drink at the movies/Fast food, about 22-34oz?</b>	Sm Med Lg Other: specify _____ Don't know/refused

*Hot tap water use at home*

The next questions I'm going to ask are about hot drinks made with home tap water. *[Hot water means that she boiled the water on the stove or in a microwave to get it hot. Hot water from the tap or from a hot shot should be included in the 'cold water' drinks. Include both filtered and unfiltered tap water.]*

<b>B12a. How many cups of hot drinks made from home tap water, such as coffee, tea including brewed iced tea, hot chocolate or cup-a-soups, do you usually drink per day?</b>	____ # of cups per day → if 0 skip to B13a. ____ <1 per day → B13a DK/ refused → to B13a.
---	---

<b>B12b. Are those cups usually small like a tea cup, about 4-10 oz; medium like a coffee mug, about 12-14oz; or large like an travel mug or oversized coffee mug, about 16-24oz?</b>	Sm Med Lg Other: specify _____ don't know/refused
---	--

*Bottled water*

Now I'm going to ask you some questions about your bottled water use. Try to answer the following questions as closely to what you usually or typically drink per day. Bottled water includes water that you purchase in bottles or plastic jugs and that you get from any water cooler, but not from a water fountain. Bottled water can include spring water, mineral water, distilled water, or sparkling water such as Quibell, Poland Spring, Perrier, Calistoga, some is flavored. Do not include tonic water, club soda, soda water, seltzer or caffeinated water about which we already asked you earlier.

*She should include Vitamin water and Fruit flavored water (distilled water with citric acid, flavors and electrolytes). Seltzer is different from sparkling water. Sparkling water is usually made with spring water whereas seltzer is usually made with tap water]*

**B13a. Currently, how much of all the water you drink is bottled water, including water used for hot and cold drinks? Is it all or nearly all, most, some, very little or none of the water?**

All or nearly all

Most

Some → skip to B14.

Very little → skip to B14.

none → skip to B14.

don't know/refused → skip to B14.

*[if woman says she drinks bottles of water rather than glasses, in Q14b. ask her the number of bottles and in Q14c. ask her the size of the bottle]*

<b>B13b. How many glasses of bottled water do you usually drink per day?</b>	____ # of glasses per day → if 0 skip to B14. ____ <1 per day → skip to B14. Don't know/refused
<b>B13c Are those glasses usually small like a juice glass, about 4-10oz; medium like a water glass, about 12-20; or large like a giant size drink at the movies/Fast food, about 22-34oz?</b>  <b>OR for Bottles:</b>	Sm Med Lg Other: specify _____  or

<p><b>A small bottle, about 8-12 oz; a medium bottle, about 14-24oz. and a large bottle is 26-34oz.</b></p>	<p>small bottle [8-12] medium [14-24] large bottle [26-34] Other: specify _____</p>
<p><b>B13d. What is the primary brand of bottled water that you usually drink? [note brand name]</b></p>	<p><input type="checkbox"/> Brand name _____ <input type="checkbox"/> Name of store _____ [if filling bottle at store] <input type="checkbox"/> No specific brand <input type="checkbox"/> Don't know/refused</p>

*Filtering*

*[Ask B14-B19a. for each residence in which she has lived during the past 4 months, one residence at a time]*

**B14. Do you, in any way, filter any of your tap water at \_\_\_\_\_ [street address]?**  
yes    no → skip to B20a.    don't know/refused

**B15. Is the water filtering system at \_\_\_\_\_ [street address], for the entire house or at specific locations such as a faucet, showerhead, or a pitcher?**  
entire house  
Specific locations → skip to B17a.

**B16. What is the brand name of the filter you used for the entire house?**  
\_\_\_\_\_ brand name → skip to B20a.

**B17a. Do you have a filter on your showerhead?**  
yes    no → skip to D18a.    don't know/refused → skip to B18a

**B17b. What is the brand name of the filter on the showerhead?**  
\_\_\_\_\_

**B17c. How often do you replace the filter?**  
\_\_\_\_\_ # times per month / year

**B18a. How much of the tap water you drink at \_\_\_\_\_ [street address] is filtered, including water used for hot and cold drinks? Is it \_\_\_\_\_ [read choices]?**  
All or nearly all  
Most  
Some → skip to B19a.  
Very little → skip to B19a.  
none → skip to B19a.  
don't know/refused → skip to B19a.

**B18b. Is the filter you used for the water you drink at home, at the faucet, part of the refrigerator, or a filtering pitcher such as Brita or PUR? [mark all that apply]**

**B18c. What brand is the filter on the \_\_\_\_\_? [check spelling of brand name]**

**B18d. How often do you replace the filter in the \_\_\_\_\_? [if never code 0]**

	brand name	replacement
<input type="checkbox"/> faucet	_____ brand	_____ # times per month
<input type="checkbox"/> refrigerator	_____ name	_____ / year
<input type="checkbox"/> pitcher	_____ brand	_____ # times per month
<input type="checkbox"/> other	_____ name	_____ / year
<input type="checkbox"/> don't know	_____ brand	_____ # times per month
/refused	_____ name	_____ / year
	_____ brand	_____ # times per month
	_____ name	_____ / year

**B19a. How much of the tap water you used for cooking at \_\_\_\_\_ [street address] is filtered? Is it \_\_\_\_\_ [read choices]?**

All or nearly all

Most

Some

Very little

none

don't know/refused

*[Ask B14-B19a. for each of the residences before continuing with B20a.]*

**B20a. How much of the tap water you drink outside your home is filtered, including water used for hot and cold drinks? Is it \_\_\_\_ [read choices]? [interviewer note: 'outside home' would include any place where she drinks a significant amount of her water such as at work, restaurants, friend's home.]**

☐ All or nearly all

☐ Most

☐ Some → skip to B21. if B14 is yes; if B14 is no skip to B22a.

☐ Very little → skip to B21. if B14 is yes; if B14 is no skip to B22a.

☐ None → skip to B21. if B14 is yes; if B14 is no skip to B22a.

☐ don't know/refused → skip to B21. if B14 is yes; if B15 is no skip to B22a.

**B20b. Is the filter you used for the tap water you drink outside your home, at the faucet, part of a refrigerator, or a filtering pitcher such as Brita or PUR? [mark all that apply]**

**B20c. What brand is the filter in the \_\_\_\_\_? [only ask for pitcher or other]**

**B20d. How often do you replace the filter in the \_\_\_\_\_? [only ask for pitcher or other]**

	brand name	replacement
<input type="checkbox"/> faucet		
<input type="checkbox"/> refrigerator		
<input type="checkbox"/> pitcher	_____	_____ # times per
<input type="checkbox"/> other	brand name	month / year
<input type="checkbox"/> don't know	_____	_____ # times per
/refused	brand name	month / year

**B21. Thinking about the filters you use both at home and outside your home, when replacing any of these filters, how do you decide when to replace it? Is it \_\_\_\_\_ [read choices, mark all that apply]?**

- ☐ based on manufacturer recommendations  
☐ when the water begins to taste bad  
☐ when you remember  
☐ other [specify] \_\_\_\_\_

Now I'm going to ask you about other uses of water in your home such as for showering, bathing, bathing children, and washing dishes and clothes. Again, think about what you do in a typical week.

#### *Showering*

**B22a. How often do you shower at home?**

\_\_\_\_\_ times per day/week/month [If < 2x per week, skip to B23a. ]  
 \_\_\_\_\_ < 1x month → skip to B23a.

**B22b. How many minutes do you usually spend actually in the shower?**

\_\_\_\_\_ # minutes

**B22c. How many minutes do you usually spend in the bathroom with the door closed while the shower is running before getting in?**

\_\_\_\_\_ #minutes

**B22d. How many minutes do you usually spend in the bathroom with the door closed after you'd showered?**

\_\_\_\_\_ # minutes

#### *Bathing*

**B23a. How often do you take a bath at home, not including showers? [interviewer note: include if she takes a bath with her children]**

\_\_\_\_\_ times per day/week/month [if < 2x per week, skip to B24a.]  
 \_\_\_\_\_ < 1x month → skip to B24a.

**B23b. When you took a bath, how full was the tub:  $\frac{1}{4}$ ,  $\frac{1}{2}$ ,  $\frac{3}{4}$ , or completely full?** *[refers to how submerged she is]*  
 $\frac{1}{4}$        $\frac{1}{2}$        $\frac{3}{4}$       full

**B23c. How many minutes do you usually spend in the tub?**  
 \_\_\_\_\_ # minutes

**B23d. How many minutes do you usually spend in the bathroom with the door closed while the bathtub is filling up before getting in?**  
 \_\_\_\_\_ #minutes

**B23e. How many minutes do you usually spend in the bathroom with the door closed after you'd bathed?**  
 \_\_\_\_\_ #minutes

*Children*

**B24a. At home, how often do you bathe infants or small children, those too young to leave alone in the bath tub?** *[do not include times when she takes a bath with her children, this should be included in B23a]*  
 \_\_\_\_\_ # times per day / per week / per month *[if < 2 bath per week skip to B25a.]*  
 \_\_\_\_\_ < 1x month *[if < 2 bath per week skip to B25a.]*

**B24b. How many minutes per bath do you usually spend bathing children?**  
 \_\_\_\_\_ minutes per bath

**B24c. How many minutes do you usually spend in the bathroom with the door closed while the bath is filling before you bathe children?**  
 \_\_\_\_\_ #minutes

**B24d. How many minutes do you usually spend in the bathroom with the door closed after you'd bathed children?**  
 \_\_\_\_\_ # minutes

*Dishes*

**B25a. How often do you typically rinse or wash dishes by hand?**  
 \_\_\_\_\_ # times per day / week / month *[if less than twice per week → Skip to B26a.]*  
 \_\_\_\_\_ < 1x month *[if less than twice per week → Skip to B26a.]*

**B25b. How much time do you usually spend on each occasion rinsing or washing dishes by hand?**  
 \_\_\_\_\_ #minutes / hours per occasion

**B25c. How often do you use gloves when washing the dishes, all of the time, most of the time, some of the time, or very rarely?**

- ☐ All the time  
☐ Most of the time  
☐ Some of the time  
☐ Rarely or never  
☐ Refused/Don't know

*Clothes*

**B26a. How often do you wash clothing by hand instead of machine?**

\_\_\_\_\_ # times per week / month / never [if < 2x per week → skip to Section C]  
 \_\_\_\_\_ < 1x month [if < 2x per week → skip to Section C]

**B26b. How much time do you usually spend each time you wash clothes by hand?**

\_\_\_\_\_ #minutes / hours per occasion

**B26c. How often do you use gloves when washing clothing by hand, all of the time, most of the time, some of the time, or very rarely?**

- ☐ All the time  
☐ Most of the time  
☐ Some of the time  
☐ Rarely or never  
☐ Don't know/refused

Now I'm going to ask you about other water-related activities outside of the home such as swimming and hot tub/jacuzzi usage. Again, think about what you do in a typical week.

*Time in the pool*

The following questions are about the time you spent in the water at either an indoor or outdoor swimming pool. Think about the time you were swimming, doing water aerobics, playing with children or any other activity that was in the water. Please do not include time you spent out of the water at pools.

**B27a. Currently, how often do you spend any time in the water at an indoor or outdoor pool, including while swimming, doing water aerobics or other exercise, or playing with children?**

\_\_\_\_\_ #times per day / per week / per month [if less than 1x per week → skip to B28a.]

**B27b. How long do you usually spend in the water each time you go to the pool?**

\_\_\_\_\_ # minutes      \_\_\_\_\_ # hours

**B27c. Pools can be disinfected in many ways. Is the water in the pool you use most often disinfected with chlorine?**

Yes                      No                      Don't know/refused

*Time at an indoor pool*

The next few questions are about time you spent out of the water at an indoor pool only.

**B28a. Currently, how often do you spend time at the indoor pool when you are not in the water such as while watching children swim?**

\_\_\_\_\_ times per day/week/month *[if less than 1x per week → skip to B29a.]*

**B28b. How long do you usually stay at the indoor pool each time you go?**

\_\_\_\_\_ # minutes      \_\_\_\_\_ # hours

**B28c. Pools can be disinfected in many ways. Is the water in the pool you use most often disinfected with chlorine?**

Yes                      No                      Don't know/refused

*Hot tub/Jacuzzi*

**B29a. Currently, how often do you spend any time in a hot tub or Jacuzzi?**

\_\_\_\_\_ # times per day/week/month *[if less than 2 times per week skip to C1a.]*

**B29b. How long do you usually stay in the hot tub or Jacuzzi each time you use one?**

\_\_\_\_\_ # minutes / # hours per occasion

**B29c. Hot tubs and Jacuzzis can be disinfected in many ways. Is/was the water in the hot tub or Jacuzzi you use/used most often disinfected with chlorine?**

Yes                      No                      Don't know/refused

## Section C Closing

**C1a.** We will be mailing you \$10 for completing this interview. I need to verify your current mailing address. Do you receive mail at *[get address from the screening interview data]*?

Yes → to C3. No

**C1b.** What is the correct mailing address?

street, city, state, zip code

**C2.** I also need to verify we have your correct SS# so that we can mail you the check. Is your SS# \_\_\_\_\_? *[from screening interview]*

Yes → skip to C3. No Don't know/refused

**C2b.** What is the correct number?

\_\_\_\_\_

**C2c.** *[If we didn't get a number in the screening]* We use a social security number for administrative purposes and do not disclose it for any reason. Would you give me your social security number, please?

Yes: \_\_\_\_\_ SS# No Don't know/refused

**C3.** In closing, we would like to sincerely thank you for your time and effort. Your contribution to this important study will help us greatly in our efforts to better understand the factors that influence the health of early pregnancy. We hope you will contact us again if you decide to get pregnant in the future. To remind you, we mail free pregnancy tests, as needed, for up to six months while you're trying to get pregnant.

Thank you!

**C4a.** MARK END TIME

Time interview completed: \_\_: \_\_

**C4b.** Approximate duration of interview [in minutes]:

\_\_\_\_\_ total minutes

**C5.** Number of sessions required to complete this interview. [circle one]

1 2 3 or more

*Interviewer Remarks*

**C6. The overall quality of this interview was**

- ☐ High: Woman was absolutely certain about all the information, was clear about all the various behaviors, dates, and so forth
- ☐ Generally reliable: Woman was engaged, responded to all questions but hesitated on some answers. Needed to think through dates, etc...
- ☐ Questionable: woman didn't understand some of the questions, was not paying attention to part of the interview, or was distracted.
- ☐ Unsatisfactory: the woman appeared to be making up most of the answers, or she couldn't understand most of the questions, or was not paying attention to most of the interview.

**C7. Did some other person contribute to the woman's answers?**

Yes No

Who was it? \_\_\_\_\_

**C8.** *[Skip if C6. was high or generally reliable]* **The main reason for the questionable or unsatisfactory quality of the interview was because the respondent:** *[mark all that apply]*

- ☐ Didn't know enough info regarding the topic
- ☐ Did not want to be specific
- ☐ Sounded bored or uninterested
- ☐ Sounded upset, depressed, angry
- ☐ Had poor hearing or speech
- ☐ Sounded distracted or confused
- ☐ Frequent interruptions
- ☐ Sounded embarrassed by the subject
- ☐ Sounded emotionally unstable
- ☐ Sounded physically ill
- ☐ Not comfortable with the language of the questionnaire
- ☐ Doesn't have time
- ☐ Felt interview was too long
- ☐ Other:

**Other comments you have which may affect the interpretation of the respondent's answers.**

---

---

---